K033776
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instead
women's reproductive health products

JUN 2 5 2004

Corporate Headquarters:
4370 La Jolla Village Drive, Suite 960
San Diego, CA 92122
Tel. 858.642.7515
Fax 858.623.6991

510K SUMMARY

This summary of 510K safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510K number is:_____

1. Submitter's Identification:

   Instead Inc.
   4370 La Jolla Village Drive,
   Suite 960
   San Diego, California 92122
   Telephone: 858-642-7515
   Facsimile: 858-623-6991

   Contact Person: Joe Pike, CEO/President

   Date of Summary: 11-18-03

2. Device Name: Instead Intimate Lubricant

3. Classification Name: Lubricant (21 CFR 884.5300)

4. Predicate Device:

   a. K982673 – The Just Between Us™ lubricant by Key West Fragrance & Cosmetic Factor.
   b. K983216 – CVS Personal Lubricant by San-Mar Laboratories.

5. Intended Use: Instead Intimate Lubricant is intended to enhance the comfort and ease of intimate activity and is compatible with latex and polyurethane condoms.

2001 Hutton Drive
Suite 307
Carrollton, Texas 75006
972.484.9333 tel
972.484.9336 fax
www.softcup.com

6. Device Description/ Comparison:

Instead Intimate Lubricant is a water-glycerin based lubricant that uses thickening agents for gel formation. No fragrances or petroleum-based chemicals are used in the formulation.

A comparison of the technological characteristics of the Instead Intimate Lubricant with the predicate devices (shown in the table below) substantiates the substantial equivalence of the Instead Intimate Lubricant to the predicate devices.

Table 1. Comparison of Technological Characteristics

Characteristic/ Feature	Instead Intimate Lubricant	The Just Between Us™ (K982673)	CVS Personal Lubricant (K983216)
Contains purified water	Yes	Yes	Yes
Contains glycerin	Yes	Yes	Yes
Contains thickening agents	Yes	Yes	Yes
Contains preservatives	Yes	Yes	Yes
Container Material	Plastic	Plastic	Plastic
Label Condom Compatible	Yes	Yes	Yes
Sterile	No	No	No

Non-clinical testing of the Instead Intimate Lubricant included measurement of bioadhesion, buffering capacity, effect on semen, viscosity and compatibility with latex and polyurethane condoms. Instead Intimate Lubricant had better bioadhesive properties, maintained its initial pH and viscosity better when mixed with semen than other lubricants tested. The testing with semen suggested that the Instead Intimate Lubricant may reduce sperm motility (Garg, S. 2001). Latex and polyurethane condoms were tested in accordance with ASTM D3492-02 after exposure to Instead Intimate Lubricant for up to 24 hours. No effect on condom performance was found.

In-vivo testing (penile and anal irritation) confirmed the biocompatibility of the Instead Intimate Lubricant. Additionally, a repeated dose vaginal irritation study in six women confirmed the biocompatibility of the Instead Intimate Lubricant (Amaral et al. 2000).

Amaral, E., et al. Study of the vaginal tolerance to acidform, an acid-buffering bioadhesive gel, Contraception, 60:361-366, 2000.

Garg, S., et al., Properties of a new acid-buffering bioadhesive vaginal formulation (Acidform), Contraception, 64:67-75, 2001.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 5 2004

Mr. Joe Pike
CEO/ President
Instead, Inc.
4370 La Jolla Village Drive, Suite 960
SAN DIEGO CA 92122

Re: K033776
Trade/Device Name: Instead Intimate Lubricant
Regulation Number: 21 CFR 880.6375
Regulation Name: Patient lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 85 MMS, HIS, and MOL
Dated: April 16, 2004
Received: April 19, 2004

Dear Mr. Pike:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510k Number (if Known): K033776

Device Name: Instead Intimate Lubricant

Indications for Use:

Instead Intimate Lubricant is intended to enhance the comfort and ease of intimate activity and is compatible with latex and polyurethane condoms.

Prescription Use: _____ OR Over-the-Counter Use: X
(Per 21 CFR 801.109)

Concurrence of CFRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033776